AMENDED IN ASSEMBLY AUGUST 18, 2016

AMENDED IN ASSEMBLY AUGUST 1, 2016

AMENDED IN ASSEMBLY JUNE 21, 2016

AMENDED IN SENATE MAY 31, 2016

AMENDED IN SENATE APRIL 13, 2016

SENATE BILL

No. 1193

Introduced by Senator Hill

(Principal coauthor: Assembly Member Salas) (Coauthor: Assembly Member Brough)

February 18, 2016

An act to amend Sections 2909.5, 2913, 2914, 2914.1, 2914.2, 2915, 2920, 2933, 4001, 4003, 4013, 4035, 4081, 4107, 4110, 4119.1, 4127, 4127.3, 4127.7, 4127.8, 4127.9, 4128.6, 4161, 4180, 4201, 4301, 4302, 4307, 4308, 4312, 4400, 4406, 4800, 4804.5, 4830, 4846.5, 4904, and 4905 of, to add Sections 2934.1, 2988.5, 4034, 4105.5, 4126.9, 4203.5, 4301.1, 4303.1, 4316, 4826.5, 4848.1, and 4853.7 to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, and to repeal Section 2947 of, the Business and Professions Code, to amend Section 13401.5 of the Corporations Code, and to amend Sections 1261.6 and 11164.5 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1193, as amended, Hill. Healing arts.

(1) The Psychology Licensing Law establishes the Board of Psychology to license and regulate the practice of psychology, and authorizes the board to employ all personnel necessary to carry out SB 1193 -2-

that law and to employ an executive officer, as specified. These provisions are in effect only until January 1, 2017.

This bill would extend the existence of the board and the board's authorization to employ an executive officer to January 1, 2021.

The Psychology Licensing Law defines the practice of psychology as rendering or offering to render, for a fee, psychological services involving the application of psychological principles and methods, including the diagnosis, prevention, and treatment of psychological problems and emotional and mental disorders. That law prohibits unlicensed persons from practicing psychology, but authorizes unlicensed persons, including psychological assistants who meet certain requirements and do not provide psychological services to the public, except as an employee of a licensed psychologist, licensed physician, contract clinic, psychological corporation, or medical corporation, to perform limited psychological functions. That law also prohibits its provisions from being construed as restricting or preventing specified nonprofit community agency employees from carrying out activities of a psychological nature or using their official employment title, as specified, provided the employees do not render or offer to render psychological services. That law provides that a violation of any of its provisions is a misdemeanor.

This bill would recast these provisions to authorize an unlicensed person preparing for licensure as a psychologist to perform psychological functions under certain conditions, including registration with the board as a psychological assistant and immediate supervision by a licensed psychologist or physician and surgeon who is board certified in psychiatry, as specified. The bill would prohibit a psychological assistant from providing psychological services to the public except as a supervisee. The bill would expand the prohibition on construing the Psychology Licensing Law's provisions as restricting or preventing specified activities of nonprofit community agency employees by making this prohibition contingent on the employees' not rendering or offering to render psychological services to the public. By changing the definition of a crime, this bill would create a state-mandated local program.

The Psychology Licensing Law conditions the issuance of a psychology license upon an applicant having received any of certain kinds of doctorate degrees, from an accredited educational institution. That law requires, with certain exceptions, the board to issue renewal licenses for psychology only to those applicants who have completed

-3- SB 1193

36 hours of approved continuing education in the preceding two years. Existing law prescribes a biennial license renewal fee of not more than \$500. Existing law also requires a person applying for relicensure or for reinstatement to an active license to certify under penalty of perjury that he or she is in compliance with the continuing education requirements. Existing law requires continuing education instruction to be completed within the state or be approved for credit by the American Psychological Association or its equivalent.

This bill would revise and recast the doctorate degree requirements for licensure to include, until January 1, 2020, a doctorate degree from an unaccredited institution that is approved for operation by a specified entity. The bill would replace the term "continuing education" with "continuing professional development," define "continuing professional development," require a person applying for renewal or reinstatement to certify compliance with these requirements under penalty of perjury, require continuing professional courses to be approved by organizations approved by the board, as specified, and authorize the board to grant exemptions from, or extensions for compliance with, these requirements.

This bill would authorize the board to issue a retired license to a licensed psychologist if the psychologist has applied to the board for a retired license and pays a fee of not more than \$75. The bill would also prohibit the holder of a retired license from engaging in the practice of psychology in the same manner as an active licensee. Because a violation of this prohibition would be a crime, the bill would impose a state-mandated local program.

Existing law authorizes the board to appoint qualified persons to give the whole or any portion of any examination provided for in the law, to be designated as commissioners on examination.

This bill would repeal this authorization.

This bill would authorize the board to post on its Internet Web site the prescribed information regarding all current and former licensees.

 $^{(1)}$

(2) The Pharmacy Law provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is within the Department of Consumer Affairs, and authorizes the board to appoint, with the approval of the Director of Consumer Affairs, an executive officer, as specified. That law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017. Under existing law, the board

SB 1193 —4—

is subject to evaluation by the Joint Sunset Review Committee upon its repeal.

This bill would extend the operation of the board and the board's authorization to appoint an executive officer until January 1, 2021.

The Pharmacy Law requires each application to conduct a pharmacy, wholesaler, 3rd-party logistics provider, or veterinary food-animal drug retailer to be made on a form furnished by the board and to state specified information. That law requires the executive officer to issue a license to conduct a pharmacy, wholesaler, 3rd-party logistics provider, or veterinary food-animal drug retailer, if specified conditions are met. That law authorizes the board to cancel a license if the licensed premises remains closed, as defined, other than by order of the board. That law requires a licensee whose license is canceled or who notifies the board of its intent to remain closed or to discontinue business to arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee within 10 days. That law authorizes the board to seek and obtain a specified court order authorizing the board to enter the premises, and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the premises if the licensee does not comply with the requirement to do so.

This bill would require an outsourcing facility, as defined, to be licensed with the board before doing business within or into the state. The bill would require each application to conduct an outsourcing facility to be made on a form furnished by the board and to state specified information. The bill would require the executive officer to issue a license if specified conditions are met. The bill would prohibit an outsourcing facility from being concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration (FDA) within 10 days of the action. The bill would prohibit the issuance or renewal of an outsourcing facility license until the board inspects the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to \$5,000 per occurrence. The bill would immediately cancel, revoke, or suspend by operation of law the license of any nonresident outsourcing facility whose registration is canceled, revoked, or suspended by the _5_ SB 1193

FDA. The bill would authorize the board to cancel an outsourcing facility license if the outsourcing facility remains closed, as defined, other than by order of the board. The bill would require an outsourcing facility licensee whose license is canceled or who notifies the board of its intent to remain closed or to discontinue business to arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee within 10 days. The bill would authorize the board to seek and obtain a specified court order authorizing the board to enter the outsourcing facility, and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the outsourcing facility if the licensee does not comply with the requirement to do so. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing facilities.

The Pharmacy Law requires a facility licensed by the board to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and requires a facility to update its email address within 30 days of a change in the facility's email address.

This bill would require each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative of a 3rd-party logistics provider licensed in this state to join the board's email notification list within 60 days of obtaining a license or at the time of license renewal and to update the licensee's email address within 30 days of a change in the licensee's email address. The bill would prohibit the board from posting those email addresses on the board's license verification system. The bill would make these provisions operative on July 1, 2017.

The Pharmacy Law requires the board to take action against any licensee who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or by mistake and includes, among others, gross immorality as unprofessional conduct. That law also includes the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required under the Pharmacy Law as grounds for unprofessional conduct.

This bill would delete gross immorality as unprofessional conduct and instead provide that procurement of a license by fraud or misrepresentation is unprofessional conduct. This bill would require that revocation, suspension, or other discipline by another state as the SB 1193 -6-

basis for similar action under the pharmacy law be grounds for revocation, suspension, or other discipline under the Pharmacy Law and requires the board to take action coterminously with action taken by another state. The bill would authorize the board to exceed the term of discipline of another state consistent with the board's enforcement guidelines and provide that evidence of discipline by another state is conclusive proof of unprofessional conduct. The bill would also require the board, to ensure that its resources are maximized for the protection of the public health and safety, to prioritize its investigative and prosecutorial resources to ensure that pharmacists representing the greatest threat of—actual patient harm are identified and disciplined expeditiously.

The Pharmacy Law defines "person" as including a firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision. That law authorizes the board to deny or revoke any license of a corporation, as specified. That law prohibits a person who has, among other things, been denied a license or whose license has been revoked from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee, as specified, and requires the board to notify in writing each licensee for whom a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the prohibition.

This bill would also define "person" to include, but not be limited to, a trust and would make conforming changes.

The Pharmacy Law requires that fees collected on behalf of the board be credited to the Pharmacy Board Contingent Fund. Existing law continuously appropriates fees in the fund.

This bill would authorize the board to collect a fee of \$2,270 for the issuance of an outsourcing facility license, which may be increased to up to \$3,180 by the board, a fee of \$1,325 for the renewal of that license, which may be increased to up to \$1,855 by the board, and a fee of \$715 for a temporary outsourcing facility license, as specified. The bill would authorize the board to collect a fee of \$2,380 for the issuance of a nonresident outsourcing facility license, which may be increased to up to \$3,335 by the board, and a fee of \$2,270 for the renewal of that license, which may be increased to up to \$3,180 by the board, as specified. The bill would provide that the Pharmacy Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

7 SB 1193

The Pharmacy Law requires all records of manufacture, and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices to be at all times, during business hours, open to inspection by authorized officers of the law, and to be preserved for at least 3 years from the date of making. That law requires specified entities and individuals to keep a current inventory of these records.

This bill would require an outsourcing facility to keep a current inventory of these records.

The Pharmacy Law authorizes the board to issue a temporary permit to own or operate a pharmacy when the ownership of a pharmacy is transferred from one person to another, as specified.

This bill would authorize the board to issue a temporary permit, as specified, regardless of whether the ownership of a pharmacy is transferred from one person to another.

The Pharmacy Law authorizes a pharmacy to provide pharmacy services to specified licensed health facilities through the use of an automated drug delivery system.

This bill would require a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system to register the system by providing the board in writing with the location of each automated drug delivery system within 30 days of installation and on an annual basis as part of the license renewal. The bill would also require the pharmacy to advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system. The bill would exempt from these requirements an automated drug delivery system operated by a licensed hospital pharmacy for doses administered in a facility operated under a consolidated license. The bill would authorize a pharmacy to use an automated drug delivery system only if certain conditions are satisfied, including, among other conditions, that the pharmacy report to the board drug losses from the system. The bill would authorize the board to prohibit a pharmacy from using an automated drug delivery system if the board determines that those conditions are not satisfied. The bill would require the board to provide the pharmacy with written notice, as specified, if the board determines those conditions are not satisfied. The bill would authorize the pharmacy, within 30 days of receipt of the written notice, to request an office conference to appeal the board's decision. The bill would authorize the executive officer or designee to affirm or overturn the prohibition as a result of the office conference.

SB 1193 -8-

The Pharmacy Law, until January 1, 2012, permitted access by licensed personnel to multiple drugs that are not patient specific only if an automated drug delivery system had both electronic and mechanical safeguards in place to ensure that the only drugs delivered to the patient were specific to that patient. Existing law, until January 1, 2012, required each facility using an automated drug delivery system to notify the State Department of Health Care Services in writing prior to utilization of the system, as provided. Existing law, until January 1, 2012, required the department, as part of its oversight of those facilities, to review a facility's medication training, storage, and security and its administration procedures related to its use of an automated drug delivery system. Existing law authorizes the stocking of an automated drug delivery system to be done outside the facility if the automated drug delivery system utilizes removable pockets, cards, drawers, or similar technology and if certain conditions are met, including that the removable pockets, cards, or drawers are transported in a secured tamper-evident container.

This bill would make these provisions operative by repealing the provision that made them inoperative on January 1, 2012. The bill would additionally authorize the stocking of an automated drug delivery system to be done outside the facility if the system utilizes unit of use or single dose containers, as specified.

The Pharmacy Law requires the board to issue a license, after an investigation to determine whether the applicant and the premises qualify for a license, that authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic.

This bill would require the board, when a clinic applicant submits specified types of applications, to issue a license or incorporate changes to an existing license within 30 days of receipt of a completed application and payment of fees. The bill would require that this provision not be construed to limit the board's authority to investigate to determine whether the applicant and the premises qualify for a license.

The Pharmacy Law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding. That law prohibits the board from issuing more than one site license to a single premises with specified exceptions,

-9- SB 1193

including issuing a license to compound sterile injectable drugs to a resident pharmacy.

This bill would expand the exception under which the board may issue more than one site license to a single premises to include issuing a license to compound sterile drugs to a pharmacy, regardless of whether those drugs are injectable and regardless of whether the pharmacy is a nonresident pharmacy.

The Pharmacy Law requires a pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation to possess a sterile compounding pharmacy license.

This bill would require a pharmacy that compounds any sterile drug products to possess a sterile compounding pharmacy license.

The Pharmacy Law authorizes the executive officer of the board, based on a reasonable belief obtained during an investigation or pharmacy inspection by the board, to issue a cease and desist order to a pharmacy requiring the pharmacy to refrain from compounding injectable sterile drug products if that activity poses an immediate threat to the public health or safety.

This bill would expand the authorization of the executive officer of the board to issue a cease and desist order to include requiring the pharmacy to refrain from compounding any sterile drug products if that activity poses an immediate threat to public health or safety.

The Pharmacy Law requires a pharmacy to compound injectable sterile products from one or more nonsterile ingredients in a specified environment.

This bill would require a pharmacy to compound any sterile products from one or more nonsterile ingredients in a specified environment.

The Pharmacy Law authorizes the board to issue a temporary license to compound injectable sterile drug products when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, as specified.

This bill would authorize the board to issue a temporary permit to compound sterile drug products, as specified, regardless of whether the drug product is injectable and regardless of whether the ownership of the pharmacy is transferred from one person to another.

The Pharmacy Law requires a resident or a nonresident pharmacy that issues a recall notice regarding a sterile compounded drug to contact, as specified, the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice, if use of or exposure to the recalled drug may cause serious

SB 1193 -10-

adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state.

This bill would make a technical correction to this provision and would require a pharmacy that issues a recall notice regarding a nonsterile compounded drug to contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice, if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state. The bill would also require a pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy to report the event to the MedWatch program of the federal Food and Drug Administration within 72 hours.

The Pharmacy Law authorizes specified clinics to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to the clinic's patients. That law requires each clinic location to have a separate license.

This bill would require the board to synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

Existing law authorizes specified healing arts licensees to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

This bill would additionally authorize licensed pharmacists to be shareholders, officers, directors, or professional employees of a designated professional corporation, subject to certain limitations relating to ownership of shares.

Existing law authorizes, with the approval of the board and the Department of Justice, a pharmacy or hospital to receive electronic data transmission prescriptions and computer entry prescriptions or orders for controlled substances in Schedule II, III, IV, or V, if authorized by federal law and in accordance with regulations promulgated by the federal Drug Enforcement Administration. Existing law requires the board to maintain a list of all requests and approvals granted. Existing law prohibits an approved pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance in Schedule II, III, IV, or V from being required to reduce that prescription or order to writing or to hard copy form as

-11- SB 1193

long as the pharmacy or hospital is able to immediately produce a specified hard copy upon request.

This bill would remove these provisions.

The Pharmacy Law makes a violation of any of its provisions punishable as a misdemeanor or an infraction, as specified.

By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program.

(2)

(3) The Veterinary Medicine Practice Act provides for the licensure and registration of veterinarians and registered veterinary technicians and the regulation of the practice of veterinary medicine by the Veterinary Medical Board, which is within the Department of Consumer Affairs, and authorizes the board to appoint an executive officer, as specified.

Existing law repeals the provisions establishing the board and authorizing the board to appoint an executive officer as of January 1, 2017.

This bill would extend the operation of the board and the authorization of the board to appoint an executive officer until January 1, 2021. The bill would authorize a veterinarian or registered veterinary technician who is under the direct supervision of a licensed veterinarian to compound a drug for animal use pursuant to federal law and regulations promulgated by the board and would require those regulations to, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician, and the equipment necessary for safe compounding of drugs.

The Veterinary Medicine Practice Act exempts certain persons from the requirements of the act, including a veterinarian employed by the University of California or the Western University of Health Sciences while engaged in the performance of specified duties. That act requires all premises where veterinary medicine, dentistry, and surgery is being practiced to register with the board. The Veterinary Medicine Practice Act makes a violation of any of its provisions punishable as a misdemeanor.

This bill would instead require a veterinarian engaged in the practice of veterinary medicine employed by the University of California or by the Western University of Health Sciences and engaged in the performance of specified duties to be licensed as a veterinarian in the state or be issued a university license, as specified. The bill would

SB 1193 -12-

authorize an individual to apply for and be issued a university license if he or she meets certain requirements, including paying an application and license fee. The bill would require a university license, among other things, to automatically cease to be valid upon termination or cessation of employment by the University of California or the Western University of Health Sciences. The bill would also prohibit a premise registration that is not renewed within 5 years after its expiration from being renewed, restored, reissued, or reinstated; however, the bill would authorize a new premise registration to be issued to an applicant if no fact, circumstance, or condition exists that would justify the revocation or suspension of the registration if the registration was issued and if specified fees are paid. By requiring additional persons to be licensed under the act that were previously exempt, the bill would expand the definition of an existing crime and, therefore, would result in a state-mandated local program.

The Veterinary Medicine Practice Act requires all fees collected on behalf of the board to be deposited into the Veterinary Medical Board Contingent Fund, which continuously appropriates fees deposited into the fund.

This bill would provide that the Veterinary Medical Board Contingent Fund is available for expenditure only upon an appropriation by the Legislature.

(3) The Pharmacy Law makes a violation of any of its provisions punishable as an infraction if no other penalty is provided. The Veterinary Medicine Practice Act makes a violation of any of its provisions punishable as a misdemeanor.

By placing new requirements on a pharmacy, this bill would expand an existing crime and would, therefore, impose a state-mandated local program. The bill would also expand the definition of an existing crime and, therefore, result in a state-mandated local program by requiring additional persons to be licensed under the act that were previously exempt.

- (4) This bill would incorporate additional changes in Section 4400 of the Business and Professions Code proposed by SB 1039 that would become operative only if SB 1039 and this bill are both chaptered and become effective on or before January 1, 2017, and this bill is chaptered last.
- (5) This bill would incorporate additional changes in Section 4830 of the Business and Professions Code proposed by SB 1039 that would become operative only if SB 1039 and this bill are both chaptered and

-13- SB 1193

become effective on or before January 1, 2017, and this bill is chaptered last.

The

23

24

25

26

27

(6) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 2909.5 of the Business and Professions 2 Code is amended to read:

3 2909.5. This chapter shall not be construed as restricting or 4 preventing activities of a psychological nature or the use of the official title of the position for which persons were employed on the part of persons who meet the educational requirements of subdivision (b) of Section 2914 and who have one year or more of the supervised professional experience referenced in subdivision (c) of Section 2914, if they are employed by nonprofit community 10 agencies that receive a minimum of 25 percent of their financial 11 support from any federal, state, county, or municipal governmental 12 organizations for the purpose of training and providing services, 13 provided those persons are performing those activities as part of 14 the duties for which they were employed, are performing those 15 activities solely within the confines of or under the jurisdiction of the organization in which they are employed and do not render or 16 17 offer to render psychological-services, services to the public, as 18 defined in Section 2903. Those persons shall be registered by the 19 agency with the board at the time of employment and shall be 20 identified in the setting as a "registered psychologist." Those 21 persons shall be exempt from this chapter for a maximum period 22 of 30 months from the date of registration.

- SEC. 2. Section 2913 of the Business and Professions Code is amended to read:
- 2913. A person other than a licensed psychologist may—be employed by a licensed psychologist, by a licensed physician and surgeon who is board certified in psychiatry by the American Board

SB 1193 —14—

of Psychiatry and Neurology, by a clinic that provides mental health services under contract pursuant to Section 5614 of the Welfare and Institutions Code, by a psychological corporation, by a licensed psychology clinic as defined in Section 1204.1 of the Health and Safety Code, or by a medical corporation to perform limited psychological functions perform psychological functions in preparation for licensure as a psychologist only if all of the following apply: conditions are met:

- (a) The person is termed shall register himself or herself with the board as a "psychological assistant." This registration shall be renewed annually in accordance with regulations adopted by the board.
- (b) The person (1) has completed a master's degree in psychology or education with the field of specialization in psychology or counseling psychology, or (2) has been admitted to candidacy for a doctoral degree in psychology or education with the field of specialization in psychology or counseling psychology, after having satisfactorily completed three or more years of postgraduate education in psychology and having passed preliminary doctoral examinations, or (3) has completed a doctoral degree that qualifies for licensure under Section—2914, in an accredited or approved university, college, or professional school located in the United States or Canada. 2914.
- (c) (1) The person psychological assistant is at all times under the immediate supervision, as defined in regulations adopted by the board, of a licensed psychologist, or board certified psychiatrist, a licensed physician and surgeon who is certified in psychiatry by the American Board of Psychiatry and Neurology or the American College of Osteopathic Board of Neurology and Psychiatry, who shall be responsible for insuring that the extent, kind, and quality of the psychological services he or she that the psychological assistant performs are consistent with his or her training and experience and be responsible for his or her the psychological assistant's compliance with this chapter and regulations duly adopted hereunder, including those provisions set forth in Section 2960. regulations.
- (d) (1) The licensed psychologist, board certified psychiatrist, contract clinic, psychological corporation, or medical corporation, has registered the psychological assistant with the board. The

15 SB 1193

registration shall be renewed annually in accordance with regulations adopted by the board.

(2) No–A licensed psychologist may register, employ, or supervise more than three psychological assistants at any given time unless specifically authorized to do so by the board. No or board certified psychiatrist may register, employ, or shall not supervise more than one three psychological assistant assistants at any given time. No contract clinic, psychological corporation, or medical corporation may employ more than 10 assistants at any one time. No contract clinic may register, employ, or provide supervision for more than one psychological assistant for each designated full-time staff psychiatrist who is qualified and supervises the psychological assistants. No psychological assistant psychological assistant may provide psychological services to the public except as an employee of a licensed psychologist, licensed physician, contract clinic, psychological corporation, or medical corporation. a supervisee pursuant to this section.

18 (c

- (d) The psychological assistant shall comply with regulations that the board may, from time to time, duly adopt relating to the fulfillment of requirements in continuing education.
- (f) No person shall practice as a psychological assistant who is found by the board to be in violation of Section 2960 and the rules and regulations duly adopted pursuant to that section.
- SEC. 3. Section 2914 of the Business and Professions Code is amended to read:
- 2914. Each applicant for licensure shall comply with all of the following requirements:
- (a) Is not subject to denial of licensure under Division 1.5 (commencing with Section 475).
- (b) (1)—Possess an earned doctorate degree—(A) (1) in psychology,—(B) (2) in educational psychology, or—(C) (3) in education with the field of specialization in counseling psychology or educational psychology. Except as provided in subdivision—(g), (h), this degree or training shall be obtained from an accredited university, college, or professional school. The board shall make the final determination as to whether a degree meets the requirements of this section.
- 39 (c) (1) On or after January 1, 2020, possess an earned doctorate 40 degree in psychology, in educational psychology, or in education

SB 1193 -16-

with the field of specialization in counseling psychology or educational psychology from a college or institution of higher education that is accredited by a regional accrediting agency recognized by the United States Department of Education. Until *January 1, 2020, the board may accept an applicant who possesses* a doctorate degree in psychology, educational psychology, or in education with the field of specialization in counseling psychology or educational psychology from an institution that is not accredited by an accrediting agency recognized by the United States Department of Education, but is approved to operate in this state by the Bureau for Private Postsecondary Education.

(2) Paragraph (1) does not apply to any student who was enrolled in a doctoral program in psychology, educational psychology, or in education with the field of specialization in counseling psychology or educational psychology at a nationally accredited or approved institution as of December 31, 2016.

(2)

(3) No educational institution shall be denied recognition as an accredited academic institution solely because its program is not accredited by any professional organization of psychologists, and nothing in this chapter or in the administration of this chapter shall require the registration with the board by educational institutions of their departments of psychology or their doctoral programs in psychology.

(3)

(4) An applicant for licensure trained in an educational institution outside the United States or Canada shall demonstrate to the satisfaction of the board that he or she possesses a doctorate degree in psychology that is equivalent to a degree earned from a regionally accredited university in the United States or Canada. These applicants shall provide the board with a comprehensive evaluation of the degree performed by a foreign credential evaluation service that is a member of the National Association of Credential Evaluation Services (NACES), and any other documentation the board deems necessary.

36 (e)

(d) (1) Have engaged for at least two years in supervised professional experience under the direction of a licensed psychologist, the specific requirements of which shall be defined by the board in its regulations, or under suitable alternative

-17- SB 1193

supervision as determined by the board in regulations duly adopted under this chapter, at least one year of which shall be after being awarded the doctorate in psychology. The supervisor shall submit verification of the experience required by this subdivision to the trainee in a manner prescribed by the board. If the supervising licensed psychologist fails to provide verification to the trainee in a timely manner, the board may establish alternative procedures for obtaining the necessary documentation. Absent good cause, the failure of a supervising licensed psychologist to provide the verification to the board upon request shall constitute unprofessional conduct.

(2) The board shall establish qualifications by regulation for supervising psychologists.

(d)

(e) Take and pass the examination required by Section 2941 unless otherwise exempted by the board under this chapter.

(e)

(f) Show by evidence satisfactory to the board that he or she has completed training in the detection and treatment of alcohol and other chemical substance dependency. This requirement applies only to applicants who matriculate on or after September 1, 1985.

(f)

- (g) (1) Show by evidence satisfactory to the board that he or she has completed coursework in spousal or partner abuse assessment, detection, and intervention. This requirement applies to applicants who began graduate training during the period commencing on January 1, 1995, and ending on December 31, 2003.
- (2) An applicant who began graduate training on or after January 1, 2004, shall show by evidence satisfactory to the board that he or she has completed a minimum of 15 contact hours of coursework in spousal or partner abuse assessment, detection, and intervention strategies, including knowledge of community resources, cultural factors, and same gender abuse dynamics. An applicant may request an exemption from this requirement if he or she intends to practice in an area that does not include the direct provision of mental health services.
- (3) Coursework required under this subdivision may be satisfactory if taken either in fulfillment of other educational requirements for licensure or in a separate course. This requirement

SB 1193 —18—

1 for coursework shall be satisfied by, and the board shall accept in 2 satisfaction of the requirement, a certification from the chief 3 academic officer of the educational institution from which the 4 applicant graduated that the required coursework is included within 5 the institution's required curriculum for graduation.

(g) An

- (h) Until January 1, 2020, an applicant holding a doctoral degree in psychology from an approved institution is deemed to meet the requirements of this section if both of the following are true:
- (1) The approved institution offered a doctoral degree in psychology designed to prepare students for a license to practice psychology and was approved by the former Bureau for Private Postsecondary and Vocational Education on or before July 1, 1999.
- (2) The approved institution has not, since July 1, 1999, had a new location, as described in Section 94823.5 of the Education Code.
- SEC. 4. Section 2914.1 of the Business and Professions Code is amended to read:
- 2914.1. The board shall encourage every licensed psychologist to take-a continuing education course in geriatric pharmacology as a part of his or her continuing education. professional development in geriatric pharmacology.
- SEC. 5. Section 2914.2 of the Business and Professions Code is amended to read:
- 2914.2. The board shall encourage licensed psychologists to take continuing education courses professional development in psychopharmacology and biological basis of behavior as part of their continuing education. behavior.
- SEC. 6. Section 2915 of the Business and Professions Code is amended to read:
- 2915. (a) Except as provided in this section, on or after January 1, 1996, the board shall not issue any renewal license unless the applicant submits proof that he or she has completed no less than 18 hours of approved continuing education in the preceding year. On or after January 1, 1997, except as provided in this section, the board shall issue renewal licenses only to those applicants who
- 38 have a renewal license only to an applicant who has completed
- 39 36 hours of approved continuing—education professional
- *development* in the preceding two years.

-19- SB 1193

(b) Each person-renewing who applies to renew or reinstate his or her license issued pursuant to this chapter shall-submit proof of certify under penalty of perjury that he or she is in compliance with this section to the board. and shall retain proof of this compliance for submission to the board upon request. False statements submitted pursuant to this section shall be a violation of Section 2970.

- (c) A person applying for relicensure or for reinstatement to an active license status shall certify under penalty of perjury that he or she is in compliance with this section.
- (d) (1) The continuing education requirement shall include, but shall not be limited to, courses required pursuant to Sections 25 and 28. The requirement may include courses pursuant to Sections 32 and 2914.1.
- (c) Continuing professional development means certain continuing education learning activities approved in four different categories:
 - (1) Professional.
- (2) Academic.

- (3) Sponsored continuing education coursework.
- (4) Board certification from the American Board of Professional Psychology.

The board may develop regulations further defining acceptable continuing professional development activities.

(2) (A)

(d) (1) The board shall require a licensed psychologist who began graduate study prior to January 1, 2004, to take a continuing education course during his or her first renewal period after the operative date of this section in spousal or partner abuse assessment, detection, and intervention strategies, including community resources, cultural factors, and same gender abuse dynamics. Equivalent courses in spousal or partner abuse assessment, detection, and intervention strategies taken prior to the operative date of this section or proof of equivalent teaching or practice experience may be submitted to the board and at its discretion, may be accepted in satisfaction of this requirement.

37 (B)

(2) Continuing education courses taken pursuant to this paragraph *subdivision* shall be applied to the 36 hours of approved

SB 1193 -20-

continuing—education professional development required under subdivision (a).

- (C) A licensed psychologist whose practice does not include the direct provision of mental health services may apply to the board for an exemption from the requirements of this paragraph.
- (e) Continuing education—instruction courses approved to meet the requirements of this section shall be completed within the State of California, or shall be approved for continuing education credit by the American Psychological Association or its equivalent as approved by organizations approved by the board. An organization previously approved by the board to provide or approve continuing education is deemed approved under this section.
- (e) The board may establish a policy for exceptions from the continuing education requirement of this section.
- (f) The board may—recognize accept continuing education courses that have been approved by one or more private nonprofit organizations that have at least 10 years' experience managing continuing education programs for psychologists on a statewide basis, including, but not limited to: approved by an entity that has demonstrated to the board in writing that it has, at a minimum, a 10-year history of providing educational programming for psychologists and has documented procedures for maintaining a continuing education approval program. The board shall adopt regulations necessary for implementing this section.
 - (1) Maintaining and managing related records and data.
 - (2) Monitoring and approving courses.
- (g) The board shall adopt regulations as necessary for implementation of this section.
- (h) A licensed psychologist shall choose continuing education instruction that is related to the assessment, diagnosis, and intervention for the client population being served or to the fields of psychology in which the psychologist intends to provide services, that may include new theoretical approaches, research, and applied techniques. Continuing education instruction shall include required courses specified in subdivision (d).
- (i) A psychologist shall not practice outside his or her particular field or fields of competence as established by his or her education, training, continuing education, and experience.

—21— SB 1193

(g) The board may grant an exemption, or an extension of the time for compliance with, from the continuing professional development requirement of this section.

(j)

- (h) The administration of this section may be funded through professional license fees and continuing education provider and course approval fees, or both. The fees related to the administration of this section shall not exceed the costs of administering the corresponding provisions of this section.
- (k) Continuing education credit may be approved for those licensees who serve as commissioners on any examination pursuant to Section 2947, subject to limitations established by the board.
 - (1) This section shall become operative on January 1, 2004.
- SEC. 7. Section 2920 of the Business and Professions Code is amended to read:
- 2920. (a) The Board of Psychology shall enforce and administer this chapter. The board shall consist of nine members, four of whom shall be public members.
- (b) This section shall remain in effect only until January 1, 2017, 2021, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. repealed.
- (c) Notwithstanding any other provision of law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.
- SEC. 8. Section 2933 of the Business and Professions Code is amended to read:
- 2933. (a) Except as provided by Section 159.5, the board shall employ and shall make available to the board within the limits of the funds received by the board all personnel necessary to carry out this chapter. The board may employ, exempt from the State Civil Service Act, an executive officer to the Board of Psychology. The board shall make all expenditures to carry out this chapter. The board may accept contributions to effectuate the purposes of this chapter.

36 This

(b) This section shall remain in effect only until January 1, 2017, 2021, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date. repealed.

SB 1193 -22-

1 SEC. 9. Section 2934.1 is added to the Business and Professions 2 Code, to read:

- 2934.1. (a) The board may post on its Internet Web site the following information on the current status of the license for all current and former licensees:
- (1) Whether or not the licensee has a record of a disciplinary action.
- (2) Any of the following enforcement actions or proceedings against the licensee:
 - (A) Temporary restraining orders.
 - (B) Interim suspension orders.
- (C) Revocations, suspensions, probations, or limitations on practice ordered by the board or by a court with jurisdiction in the state, including those made part of a probationary order, cease practice order, or stipulated agreement.
- (D) Accusations filed by the board, including those accusations that are on appeal, excluding ones that have been dismissed or withdrawn where the action is no longer pending.
- (E) Citations issued by the board. Unless withdrawn, citations shall be posted for five years from the date of issuance.
- (b) The board may also post on its Internet Web site all of the following historical information in its possession, custody, or control regarding all current and former licensees:
- (1) Institutions that awarded the qualifying educational degree and type of degree awarded.
- (2) A link to the licensee's professional Internet Web site. Any link that provides access to a licensee's professional Internet Web site, once clicked, shall be accompanied by a notification that informs the Internet Web site viewer that they are no longer on the board's Internet Web site.
- (c) The board may also post other information designated by the board in regulation.
- SEC. 10. Section 2947 of the Business and Professions Code is repealed.
- 2947. The board may appoint qualified persons to give the whole or any portion of any examination provided for in this chapter, who shall be designated as commissioners on examination. A commissioner on examination need not be a member of the
- A commissioner on examination need not be a member of the board but he or she shall have the same qualifications as a member
- 40 of the board, including those set forth in Chapter 6 (commencing

23 SB 1193

with Section 450) of Division 1. The board may also appoint occasional professional commissioners for short-term specified periods to assist in its nonpolicy workload.

1 2

Public commissioners may examine and evaluate candidates in areas of knowledge such as the law, ethics, and awareness of community resources.

- SEC. 11. Section 2988.5 is added to the Business and Professions Code, to read:
- 2988.5. (a) The board may issue, upon an application prescribed by the board and payment of a fee not to exceed seventy-five dollars (\$75), a retired license to a psychologist who holds a current license issued by the board, or one capable of being renewed, and whose license is not suspended, revoked, or otherwise restricted by the board or subject to discipline under this chapter.
- (b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active license is required. A psychologist holding a retired license shall be permitted to use the title "psychologist, retired" or "retired psychologist." The designation of retired shall not be abbreviated in any way.
 - (c) A retired license shall not be subject to renewal.
- (d) The holder of a retired license may apply to obtain an active status license as follows:
- (1) If that retired license was issued less than three years prior to the application date, the applicant shall meet all of the following requirements:
- (A) Has not committed an act or crime constituting grounds for denial or discipline of a license.
 - (B) Pays the renewal fee required by this chapter.
- (C) Completes the continuing professional development required for the renewal of a license within two years of the date of application for restoration.
- (D) Complies with the fingerprint submission requirements established by the board.
- (2) Where the applicant has held a retired license for three or more years, the applicant shall do all of the following:
 - (A) Submit a complete application for a new license.
- 39 (B) Take and pass the California Psychology Law and Ethics 40 Examination.

SB 1193 — 24—

1 (C) Pay all fees required to obtain a new license.

- (D) Comply with the fingerprint submission requirements established by the board.
- (E) Be deemed to have met the educational and experience requirements of subdivisions (b) and (c) of Section 2914.
- (F) Establish that he or she has not been subject to denial or discipline of a license.

SECTION 1.

- SEC. 12. Section 4001 of the Business and Professions Code is amended to read:
- 4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.
- (b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.
- (c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.
- (d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs.

25 SB 1193

1 Vacancies occurring shall be filled by appointment for the 2 unexpired term.

- (e) Each member of the board shall receive a per diem and expenses as provided in Section 103.
- (f) This section shall remain in effect only until January 1, 2021, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 2.

- SEC. 13. Section 4003 of the Business and Professions Code is amended to read:
- 4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.
- (b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.
- (c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.
- (d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.
- (e) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 3.

- SEC. 14. Section 4013 of the Business and Professions Code is amended to read:
- 4013. (a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.
- (b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.

SB 1193 -26-

16

17

18 19

20

21

22

23 24

25

26

2728

29

1 (c) An owner of two or more facilities licensed by the board 2 may comply with subdivisions (a) and (b) by subscribing a single 3 email address to the board's email notification list, where the owner 4 maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, 5 immediately transmits electronic notice of the same notification 6 to all of its licensed facilities. If an owner chooses to comply with 8 this section by using such an electronic notice system, the owner 9 shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, 10 informing the board of the single email address to be utilized by 11 the owner, describing the electronic notice system, and listing all 12 13 facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification 14 15 list within 30 days of any change in the owner's email address.

- (d) (1) Each pharmacist, intern pharmacist, pharmacy technician, designated representative-3PL licensed in this state shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.
- (2) Each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in this state shall update his or her email address with the board's email notification list within 30 days of a change in the licensee's email address.
- (3) The email address provided by a licensee shall not be posted on the board's online license verification system.
- (4) The board shall, with each renewal application, remind licensees of their obligation to report and keep current their email address with the board's email notification list.
- 30 (5) This subdivision shall become operative on July 1, 2017. SEC. 4.
- 32 SEC. 15. Section 4034 is added to the Business and Professions33 Code, to read:
- 34 4034. "Outsourcing facility" means a facility that meets all of the following:
- (a) Is located within the United States of America at one address
 that is engaged in the compounding of sterile drugs and nonsterile
 drugs.

—27— SB 1193

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

- (c) Is doing business within or into California.
- (d) Is licensed with the board as an outsourcing facility pursuant to Article 7.7 (commencing with Section 4129).
- SEC. 16. Section 4035 of the Business and Professions Code is amended to read:
- 4035. "Person"-includes includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, *trust*, or political subdivision.

SEC. 5.

- SEC. 17. Section 4081 of the Business and Professions Code is amended to read:
- 4081. (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- (b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.
- (c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

SB 1193 — 28—

SEC. 6.

SEC. 18. Section 4105.5 is added to the Business and Professions Code, to read:

- 4105.5. (a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.
- (b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.
- (c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:
- (1) Use of the automated drug delivery system is consistent with legal requirements.
- (2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
- (3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.
- (4) The pharmacy license is unexpired and not subject to disciplinary conditions.
- (d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.
- (e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license

SB 1193

under Section 1250.8 of the Health and Safety Code shall be 2 exempt from the requirements of subdivision (b). 3

SEC. 7.

6 7

8

9

10 11

14

15

16

17

18 19

20

21

22

23

24 25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

- 4 SEC. 19. Section 4107 of the Business and Professions Code 5 is amended to read:
 - 4107. (a) The board shall not issue more than one site license to a single premises except as follows:
 - (1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196.
 - (2) To issue a license to compound sterile drugs to a pharmacy pursuant to Section 4127.1 or 4127.2.
- 12 (3) To issue a centralized hospital packaging license pursuant 13 to Section 4128.
 - (b) For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

SEC. 8.

- SEC. 20. Section 4110 of the Business and Professions Code is amended to read:
- 4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.
- (b) The board may, at its discretion, issue a temporary permit upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board,

SB 1193 -30-

whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

- (c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:
- (1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.
- (2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.
- (3) A licensed pharmacist is on the premises while drugs are being dispensed.
- (4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
- (5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction of, or damage to, the pharmacy and an expected restoration date.
- (6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.
- (7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

SEC. 9.

- SEC. 21. Section 4119.1 of the Business and Professions Code is amended to read:
- 4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.
- (b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

-31 - SB 1193

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

- (2) The pharmacy shall own and operate the automated drug delivery system.
- (3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.
- (4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.
- (d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.
- (e) This section shall not be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

SEC. 10.

- SEC. 22. Section 4126.9 is added to the Business and Professions Code, to read:
- 4126.9. (a) A pharmacy that issues a recall notice regarding a nonsterile compounded drug product shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply:
- (1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- (2) The recalled drug was dispensed, or is intended for use, in this state.
- (b) A recall notice issued pursuant to subdivision (a) shall be made as follows:
- 37 (1) If the recalled drug was dispensed directly to the patient, 38 the notice shall be made to the patient.

SB 1193 -32-

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

- (3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.
- (c) A pharmacy that has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy shall report the event to MedWatch within 72 hours of the pharmacy being advised.

SEC. 11.

- SEC. 23. Section 4127 of the Business and Professions Code is amended to read:
- 4127. (a) A pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article.
- (b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.
- (c) The board shall review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary for the regulations adopted by the board pursuant to subdivision (b).

SEC. 12.

- SEC. 24. Section 4127.3 of the Business and Professions Code is amended to read:
- 4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

-33- SB 1193

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

- (c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.
- (d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

SEC. 13.

- SEC. 25. Section 4127.7 of the Business and Professions Code is amended to read:
- 4127.7. A pharmacy shall compound sterile products from one or more nonsterile ingredients in one of the following environments:
- (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
 - (b) An ISO class 5 cleanroom.
- 31 (c) A barrier isolator that provides an ISO class 5 environment for compounding.

SEC. 14.

- 34 SEC. 26. Section 4127.8 of the Business and Professions Code is amended to read:
 - 4127.8. The board may, at its discretion, issue a temporary license to compound sterile drug products upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (u) of Section

SB 1193 — 34—

1 4400. When needed to protect public safety, a temporary license

- 2 may be issued for a period not to exceed 180 days, and may be
- 3 issued subject to terms and conditions the board deems necessary.
- 4 If the board determines a temporary license was issued by mistake
- or denies the application for a permanent license, the temporary
- 6 license shall terminate upon either personal service of the notice
- 7 of termination upon the licenseholder or service by certified mail,
- 8 return receipt requested at the licenseholder's address of record
- 9 with the board, whichever comes first. Neither for purposes of
- 10 retaining a temporary license nor for purposes of any disciplinary
- or license denial proceeding before the board shall the temporary
- 12 licenseholder be deemed to have a vested property right or interest
- 13 in the license.

14 15

16

17

18 19

20 21

22

23

24

2526

27

28

29

30

31 32

33

34

35

36 37

- SEC. 15.
- SEC. 27. Section 4127.9 of the Business and Professions Code is amended to read:
- 4127.9. (a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:
- (1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- (2) The recalled drug was dispensed, or is intended for use, in this state.
- (b) A recall notice issued pursuant to subdivision (a) shall be made as follows:
- (1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.
- (2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.
- (3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.
- 38 SEC. 16.
- 39 SEC. 28. Section 4128.6 of the Business and Professions Code 40 is amended to read:

-35- SB 1193

4128.6. All compounding and packaging functions specified in Section 4128 shall be performed only in the licensed centralized hospital packaging pharmacy and that pharmacy shall comply with all applicable federal and state statutes and regulations, including, but not limited to, regulations regarding compounding and, when appropriate, sterile compounding.

SEC. 17.

SEC. 29. Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.7. Outsourcing Facilities

- 4129. (a) A facility licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.
- (b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.
- (c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.
- (d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.
- (e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients.
- 4129.1. (a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within this state. The license shall be renewed annually and is not transferable.

SB 1193 -36-

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

- (c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.
- (d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:
- (1) Prior to inspection, reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.
- (2) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the outsourcing facility's premises conducted in the prior 12 months.
- (3) Prior to inspection, receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.
- (e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:
- (1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.
- (2) Notice within 24 hours of any recall notice issued by the outsourcing facility.
- (3) A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.
- (4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products.
- 4129.2. (a) An outsourcing facility that is licensed with the federal Food and Drug Administration (FDA) as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for distribution or use into this state without an outsourcing license issued by the board

37 SB 1193

pursuant to this section. The license shall be renewed annually and shall not be transferable.

- (b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.
- (c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.
- (d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:
- (1) Prior to inspection, reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.
- (2) (A) Is provided with copies of all federal and state regulatory agency inspection reports, as well as accreditation reports, and certification reports of facilities or equipment of the nonresident outsourcing facility's premises conducted in the prior 12 months.
- (B) For purposes of this paragraph, "state" refers to the state in which the nonresident outsourcing facility resides.
- (3) Prior to inspection, receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.
- (e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:
- (1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.
- (2) Notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.
- (3) A copy of any complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.
- (4) Notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.

SB 1193 -38-

4129.3. (a) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident outsourcing facilities. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

- (1) A detailed description of board activities related to the inspection and licensure of nonresident outsourcing facilities.
- (2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.
- (3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.
- (4) If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.
- (b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.
- 4129.4. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.
- (b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner

-39 — SB 1193

is charged, specifying the pertinent code section or sections and any regulations.

- (c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days after the date the request of the owner is received by the board. The president shall render a written decision within five days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.
- (d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.
- 4129.5. Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars (\$5,000) per occurrence pursuant to a citation issued by the board.
- 4129.8. The board, at its discretion, may issue a temporary license to an outsourcing facility upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

SB 1193 — 40 —

4129.9. (a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:

- (1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- (2) The recalled drug was dispensed, or is intended for use, in this state.
- (b) A recall notice issued pursuant to subdivision (a) shall be made as follows:
- (1) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber and the prescriber shall ensure the patient is notified.
- (2) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy and that pharmacy shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 18.

- SEC. 30. Section 4161 of the Business and Professions Code is amended to read:
- 4161. (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.
- (b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.
- (c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state

-41- SB 1193

or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

1 2

- (2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:
- (A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.
- (B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.
- (C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.
- (D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.
- (E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.
- (F) The third-party logistics provider is not a reverse third-party logistics provider.
 - (G) The wholesaler is not acting as a reverse distributor.
- (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:
 - (1) Its agent for service of process in this state.

SB 1193 — 42—

1 (2) Its principal corporate officers, as specified by the board, if 2 any.

- (3) Its general partners, as specified by the board, if any.
 - (4) Its owners if the applicant is not a corporation or partnership.
- (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
- (f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
- (g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.
- (h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
- (i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.
- (j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws

-43 - SB 1193

governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars (\$550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
- (*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

SEC. 19.

3

4

5

6

7

8

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

- SEC. 31. Section 4180 of the Business and Professions Code is amended to read:
- 4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:
- (A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.
- 38 (B) A primary care clinic owned or operated by a county as 39 referred to in subdivision (b) of Section 1206 of the Health and 40 Safety Code.

SB 1193 — 44—

1 2

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

- (D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.
- (E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.
- (F) A nonprofit multispecialty clinic as referred to in subdivision (*l*) of Section 1206 of the Health and Safety Code.
- (2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.
- (b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.
- (c) The board shall synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

SEC. 20.

- SEC. 32. Section 4201 of the Business and Professions Code is amended to read:
- 4201. (a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested—therein. therein or any person with management or control over the license.
- (b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:
- (1) If the applicant is a partnership or other unincorporated association, each partner or member.

SB 1193

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.

- (3) If the applicant is a limited liability company, each officer, manager, or member.
- (c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.
- (d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.
- (e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility if all of the provisions of this chapter have been complied with.
- (f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.
- (g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
- (h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous

SB 1193 — 46—

drugs and dangerous devices. The license shall be renewed annually
 and shall not be transferable.

- (i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.
- (j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

SEC. 21.

- SEC. 33. Section 4203.5 is added to the Business and Professions Code, to read:
- 4203.5. (a) Notwithstanding any other law, when a clinic applicant submits either type of application described in subdivision (b), the board shall issue a license or incorporate the reported changes, as appropriate, within 30 days of receipt of a completed application and payment of any prescribed fees.
 - (b) This section applies to the following types of applications:
 - (1) A new clinic license application filed under Section 4180.
- (2) Applications to report changes to an existing site licensed under Section 4180, including, but not limited to, changes in professional director, clinic administrator, corporate officers, change of location, or change of address.
- (c) This section shall not be construed to limit the board's authority to conduct an investigation to determine whether applicants and the premises for which an application is made qualify for a license.

SEC. 22.

- SEC. 34. Section 4301 of the Business and Professions Code is amended to read:
- 4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
 - (a) Procurement of a license by fraud or misrepresentation.
- 37 (b) Incompetence.
- 38 (c) Gross negligence.

-47- SB 1193

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

- (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
- (*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating

SB 1193 — 48—

22

23

2425

26

27

28

29 30

31

32

33 34

35

36

37

38

39

1 controlled substances or of a violation of the statutes of this state 2 regulating controlled substances or dangerous drugs shall be 3 conclusive evidence of unprofessional conduct. In all other cases, 4 the record of conviction shall be conclusive evidence only of the 5 fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order 6 to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the 10 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo 11 12 contendere is deemed to be a conviction within the meaning of 13 this provision. The board may take action when the time for appeal 14 has elapsed, or the judgment of conviction has been affirmed on 15 appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under 16 17 Section 1203.4 of the Penal Code allowing the person to withdraw 18 his or her plea of guilty and to enter a plea of not guilty, or setting 19 aside the verdict of guilty, or dismissing the accusation, 20 information, or indictment. 21

- (m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.
- (n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.
- (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including

-49 - SB 1193

regulations established by the board or by any other state or federal regulatory agency.

- (p) Actions or conduct that would have warranted denial of a license.
- (q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.
- (r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.
- (s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

SEC. 23.

1

2

3

4

5

6

7

8

10

11 12

13

14

15

16 17

18

19

20

21

22

23

24 25

26

27

28

29

30

31

32

33

34

35

36 37

38

39

- SEC. 35. Section 4301.1 is added to the Business and Professions Code, to read:
- 4301.1. In order to ensure that the board's resources are maximized for the protection of the public health and safety, the board shall prioritize its investigative and prosecutorial resources to ensure that pharmacists representing the greatest threat of actual patient harm are identified and disciplined expeditiously.

SB 1193 — 50 —

SEC. 36. Section 4302 of the Business and Professions Code is amended to read:

4302. The board may deny, suspend, or revoke any license-of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, ownership interest or where conditions exist in relation to any-officer or director officer, director, or other person with management or control of the corporation license that would constitute grounds for disciplinary action against a licensee.

SEC. 24.

- SEC. 37. Section 4303.1 is added to the Business and Professions Code, to read:
- 4303.1. If the federal Food and Drug Administration (FDA) cancels, revokes, or suspends an outsourcing facility's registration for any reason, any license issued pursuant to Section 4129.2 shall be immediately canceled, revoked, or suspended by operation of law.
- SEC. 38. Section 4307 of the Business and Professions Code is amended to read:
- 4307. (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner partner, or in any other position with management or control of a licensee as follows:
- (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

51 SB 1193

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

SEC. 39. Section 4308 of the Business and Professions Code is amended to read:

4308. Whenever a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner partner, or in any other position with management or control of a licensee as provided by Section 4307, the board shall, in each case where it has that information, notify in writing each licensee for whom the person is a manager, administrator, owner, member, officer, director, associate, or partner partner, or in any other position with management or control of the prohibition. The board shall send the notification to the licensee's address of record. The licensee shall have 30 days from the date that the notice is sent to remove and replace the prohibited person and, where appropriate, file a change of permit to reflect that change.

SEC. 25.

SEC. 40. Section 4312 of the Business and Professions Code is amended to read:

4312. (a) The board may cancel the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to

SB 1193 — 52 —

give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

- (b) If the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.
- (c) If a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility is located, authorizing the board to enter the wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility.
- (d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale

53 SB 1193

an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

- (1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.
- (2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.
- (3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.
- (e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.
- (f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

SEC. 26.

- SEC. 41. Section 4316 is added to the Business and Professions Code, to read:
- 4316. (a) The board is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure.
- (b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged,

SB 1193 — 54—

1 specifying the pertinent code section or sections and any 2 regulations.

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

SEC. 27.

 SEC. 42. Section 4400 of the Business and Professions Code is amended to read:

- 4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:
- (a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).
- (d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

55 SB 1193

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

- (f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).
- (g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).
- (h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).
- (2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).
- (i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).
- (2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).
- (j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).
- (2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars

SB 1193 — 56—

1 (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).

- (3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).
- (k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.
- (*l*) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).
- (m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.
- (n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

57 SB 1193

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

- (s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).
- (v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.
- (w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one

SB 1193 — 58—

4

5

6 7

8

10

11 12

13

14

15

16 17

18

19

20

21

22

23

24

25

26

27

28 29

30

31

32

33

34

35

36 37

38

39

thousand eight hundred fifty-five dollars (\$1,855) by the board.
The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

SEC. 42.5. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

- (a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

-59 - SB 1193

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).
- (f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).
- (g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).
- (h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).
- (2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).
- (i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).
- (2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).
- (j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section

SB 1193 -60-

4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).

- (2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).
- (3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).
- (k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.
- (*l*) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).
- (m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.
- (n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

-61- SB 1193

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

- (r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).
- (v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

— 62 — SB 1193

1

2

3

4

5

6 7

8

10

11

12

13

14 15

16 17

18 19

20

21

22

23

24

25

26 27

28

29

33

34

35

36 37

38

39

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).

- (x) The fee for the issuance of a nonresident outsourcing facility *license shall be two thousand three hundred eighty dollars (\$2,380)* and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.
- 30 (y) This section shall become operative inoperative on July 1, 31 2014. 2017, and as of January 1, 2018, is repealed. 32

SEC. 28.

- SEC. 43. Section 4406 of the Business and Professions Code is amended to read:
- 4406. All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the Controller and at the same time the entire amount shall be paid into the State Treasury and shall be credited to the Pharmacy Board Contingent Fund which is hereby created. This

-63 - SB 1193

1 contingent fund shall be available, upon appropriation of the 2 Legislature, for the use of the board.

SEC. 29.

3

6

7

8

9

10

11

14

15

16 17

18

19

20

21

22

23

24

25

26

27

28

29

30

- 4 SEC. 44. Section 4800 of the Business and Professions Code 5 is amended to read:
 - 4800. (a) There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of the following members:
 - (1) Four licensed veterinarians.
 - (2) One registered veterinary technician.
 - (3) Three public members.
- 12 (b) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.
 - (c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature. However, the review of the board shall be limited to those issues identified by the appropriate policy committees of the Legislature and shall not involve the preparation or submission of a sunset review document or evaluative questionnaire.

SEC. 30.

- SEC. 45. Section 4804.5 of the Business and Professions Code is amended to read:
- 4804.5. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.
- This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 31.

- 31 SEC. 46. Section 4826.5 is added to the Business and 32 Professions Code, to read:
- 4826.5. Notwithstanding any other law, a licensed veterinarian or a registered veterinary technician under the supervision of a licensed veterinarian may compound drugs for animal use pursuant
- 36 to Section 530 of Title 21 of the Code of Federal Regulations and
- in accordance with regulations promulgated by the board. The
- 38 regulations promulgated by the board shall, at a minimum, address
- 39 the storage of drugs, the level and type of supervision required for
- 40 compounding drugs by a registered veterinary technician, and the

SB 1193 — 64—

equipment necessary for the safe compounding of drugs. Any violation of the regulations adopted by the board pursuant to this section shall constitute grounds for an enforcement or disciplinary action.

SEC. 32.

SEC. 47. Section 4830 of the Business and Professions Code is amended to read:

4830. (a) This chapter does not apply to:

- (1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.
- (2) Regularly licensed veterinarians in actual consultation from other states.
- (3) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.
- (4) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.
- (5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.
- (6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

-65- SB 1193

(b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

- (2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:
- (A) The temporary shelter facility is established only for the purpose of the investigation.
- (B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.
 - (C) The temporary shelter facility complies with Section 4854.
- (D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.
- (E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the

SB 1193 -66-

care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.

- (c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.
- SEC. 47.5. Section 4830 of the Business and Professions Code is amended to read:
 - 4830. (a) This chapter does not apply to:
- (1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.
- (2) Regularly licensed veterinarians in actual consultation from other states.
- (3) Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.
- (4) Veterinarians employed by the University of California while engaged in the performance of duties in connection with the College of Agriculture, the Agricultural Experiment Station, the School of Veterinary Medicine, or the agricultural extension work of the university or employed by the Western University of Health Sciences while engaged in the performance of duties in connection with the College of Veterinary Medicine or the agricultural extension work of the university.
- (2) Veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case. The California licensed veterinarian shall maintain a valid veterinarian-client-patient relationship. The veterinarian providing the assistance shall not establish a veterinarian-client-patient relationship with the client by attending the case or at a future time and shall not practice veterinary medicine, open an office, appoint a place to meet patients, communicate with clients who reside within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient that is located within this state.
- (3) Veterinarians called into the state by a law enforcement agency or animal control agency pursuant to subdivision (b).

40 (5)

-67- SB 1193

(4) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

(6)

(5) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

(7)

- (6) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.
- (b) (1) For purposes of paragraph (3) of subdivision (a), a regularly licensed veterinarian in good standing who is called from another state by a law enforcement agency or animal control agency, as defined in Section 31606 of the Food and Agricultural Code, to attend to cases that are a part of an investigation of an alleged violation of federal or state animal fighting or animal cruelty laws within a single geographic location shall be exempt from the licensing requirements of this chapter if the law enforcement agency or animal control agency determines that it is necessary to call the veterinarian in order for the agency or officer to conduct the investigation in a timely, efficient, and effective manner. In determining whether it is necessary to call a veterinarian from another state, consideration shall be given to the availability of veterinarians in this state to attend to these cases. An agency, department, or officer that calls a veterinarian pursuant to this subdivision shall notify the board of the investigation.

SB 1193 -68-

(2) Notwithstanding any other provision of this chapter, a regularly licensed veterinarian in good standing who is called from another state to attend to cases that are a part of an investigation described in paragraph (1) may provide veterinary medical care for animals that are affected by the investigation with a temporary shelter facility, and the temporary shelter facility shall be exempt from the registration requirement of Section 4853 if all of the following conditions are met:

- (A) The temporary shelter facility is established only for the purpose of the investigation.
- (B) The temporary shelter facility provides veterinary medical care, shelter, food, and water only to animals that are affected by the investigation.
 - (C) The temporary shelter facility complies with Section 4854.
- (D) The temporary shelter facility exists for not more than 60 days, unless the law enforcement agency or animal control agency determines that a longer period of time is necessary to complete the investigation.
- (E) Within 30 calendar days upon completion of the provision of veterinary health care services at a temporary shelter facility established pursuant to this section, the veterinarian called from another state by a law enforcement agency or animal control agency to attend to a case shall file a report with the board. The report shall contain the date, place, type, and general description of the care provided, along with a listing of the veterinary health care practitioners who participated in providing that care.
- (c) For purposes of paragraph (3) of subdivision (a), the board may inspect temporary facilities established pursuant to this section.

SEC. 33.

- SEC. 48. Section 4846.5 of the Business and Professions Code is amended to read:
- 4846.5. (a) Except as provided in this section, the board shall issue renewal licenses only to those applicants that have completed a minimum of 36 hours of continuing education in the preceding two years.
- (b) (1) Notwithstanding any other law, continuing education hours shall be earned by attending courses relevant to veterinary medicine and sponsored or cosponsored by any of the following:

-69 - SB 1193

- 1 (A) American Veterinary Medical Association (AVMA) 2 accredited veterinary medical colleges. 3 (B) Accredited colleges or universities offering programs
 - (B) Accredited colleges or universities offering programs relevant to veterinary medicine.
 - (C) The American Veterinary Medical Association.

- (D) American Veterinary Medical Association recognized specialty or affiliated allied groups.
- (E) American Veterinary Medical Association's affiliated state veterinary medical associations.
- (F) Nonprofit annual conferences established in conjunction with state veterinary medical associations.
- (G) Educational organizations affiliated with the American Veterinary Medical Association or its state affiliated veterinary medical associations.
- (H) Local veterinary medical associations affiliated with the California Veterinary Medical Association.
 - (I) Federal, state, or local government agencies.
- (J) Providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) or approved by the American Medical Association (AMA), providers recognized by the American Dental Association Continuing Education Recognition Program (ADA CERP), and AMA or ADA affiliated state, local, and specialty organizations.
- (2) Continuing education credits shall be granted to those veterinarians taking self-study courses, which may include, but are not limited to, reading journals, viewing video recordings, or listening to audio recordings. The taking of these courses shall be limited to no more than six hours biennially.
- (3) The board may approve other continuing veterinary medical education providers not specified in paragraph (1).
- (A) The board has the authority to recognize national continuing education approval bodies for the purpose of approving continuing education providers not specified in paragraph (1).
- (B) Applicants seeking continuing education provider approval shall have the option of applying to the board or to a board-recognized national approval body.
- (4) For good cause, the board may adopt an order specifying, on a prospective basis, that a provider of continuing veterinary medical education authorized pursuant to paragraph (1) or (3) is no longer an acceptable provider.

SB 1193 — 70—

(5) Continuing education hours earned by attending courses sponsored or cosponsored by those entities listed in paragraph (1) between January 1, 2000, and January 1, 2001, shall be credited toward a veterinarian's continuing education requirement under this section.

- (c) Every person renewing his or her license issued pursuant to Section 4846.4, or any person applying for relicensure or for reinstatement of his or her license to active status, shall submit proof of compliance with this section to the board certifying that he or she is in compliance with this section. Any false statement submitted pursuant to this section shall be a violation subject to Section 4831.
- (d) This section shall not apply to a veterinarian's first license renewal. This section shall apply only to second and subsequent license renewals granted on or after January 1, 2002.
- (e) The board shall have the right to audit the records of all applicants to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a period of four years and shall make these records available to the board for auditing purposes upon request. If the board, during this audit, questions whether any course reported by the veterinarian satisfies the continuing education requirement, the veterinarian shall provide information to the board concerning the content of the course; the name of its sponsor and cosponsor, if any; and specify the specific curricula that was of benefit to the veterinarian.
- (f) A veterinarian desiring an inactive license or to restore an inactive license under Section 701 shall submit an application on a form provided by the board. In order to restore an inactive license to active status, the veterinarian shall have completed a minimum of 36 hours of continuing education within the last two years preceding application. The inactive license status of a veterinarian shall not deprive the board of its authority to institute or continue a disciplinary action against a licensee.
- (g) Knowing misrepresentation of compliance with this article by a veterinarian constitutes unprofessional conduct and grounds for disciplinary action or for the issuance of a citation and the imposition of a civil penalty pursuant to Section 4883.
- (h) The board, in its discretion, may exempt from the continuing education requirement any veterinarian who for reasons of health,

71 SB 1193

military service, or undue hardship cannot meet those requirements. Applications for waivers shall be submitted on a form provided by the board.

- (i) The administration of this section may be funded through professional license and continuing education provider fees. The fees related to the administration of this section shall not exceed the costs of administering the corresponding provisions of this section.
- (j) For those continuing education providers not listed in paragraph (1) of subdivision (b), the board or its recognized national approval agent shall establish criteria by which a provider of continuing education shall be approved. The board shall initially review and approve these criteria and may review the criteria as needed. The board or its recognized agent shall monitor, maintain, and manage related records and data. The board may impose an application fee, not to exceed two hundred dollars (\$200) biennially, for continuing education providers not listed in paragraph (1) of subdivision (b).
- (k) (1) Beginning January 1, 2018, a licensed veterinarian who renews his or her license shall complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs every four years as part of his or her continuing education requirements.
- (2) For purposes of this subdivision, "medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

SEC. 34.

- SEC. 49. Section 4848.1 is added to the Business and Professions Code, to read:
- 4848.1. (a) A veterinarian engaged in the practice of veterinary medicine, as defined in Section 4826, employed by the University of California and engaged in the performance of duties in connection with the School of Veterinary Medicine or employed by the Western University of Health Sciences and engaged in the performance of duties in connection with the College of Veterinary Medicine shall be issued a university license pursuant to this

SB 1193 — 72 —

section or hold a license to practice veterinary medicine in this state.

- (b) An individual may apply for and be issued a university license if all of the following are satisfied:
- (1) He or she is currently employed by the University of California or Western University of Health Sciences, as defined in subdivision (a).
- (2) He or she passes an examination concerning the statutes and regulations of the Veterinary Medicine Practice Act, administered by the board, pursuant to subparagraph (C) of paragraph (2) of subdivision (a) of Section 4848.
- (3) He or she successfully completes the approved educational curriculum described in paragraph (5) of subdivision (b) of Section 4848 on regionally specific and important diseases and conditions.
- (4) He or she completes and submits the application specified by the board and pays the application fee, pursuant to subdivision (g) of Section 4905, and the initial license fee, pursuant to subdivision (h) of Section 4905.
 - (c) A university license:
 - (1) Shall be numbered as described in Section 4847.
- (2) Shall automatically cease to be valid upon termination or cessation of employment by the University of California or by the Western University of Health Sciences.
- (3) Shall be subject to the license renewal provisions in Section 4846.4 and the payment of the renewal fee pursuant to subdivision (i) of Section 4905.
- (4) Shall be subject to denial, revocation, or suspension pursuant to Sections 480, 4875, and 4883.
- (5) Authorizes the holder to practice veterinary medicine only at an educational institution described in subdivision (a) and any locations formally affiliated with those institutions.
- (d) An individual who holds a university license is exempt from satisfying the license renewal requirements of Section 4846.5.
- 34 SEC. 35.
- 35 SEC. 50. Section 4853.7 is added to the Business and 36 Professions Code, to read:
- 4853.7. A premise registration that is not renewed within five years after its expiration may not be renewed and shall not be restored, reissued, or reinstated thereafter. However, an application

73 SB 1193

for a new premise registration may be submitted and obtained if both of the following conditions are met:

- (a) No fact, circumstance, or condition exists that, if the premise registration was issued, would justify its revocation or suspension.
- (b) All of the fees that would be required for the initial premise registration are paid at the time of application.

SEC. 36.

- SEC. 51. Section 4904 of the Business and Professions Code is amended to read:
- 4904. All fees collected on behalf of the board and all receipts of every kind and nature shall be reported each month for the month preceding to the Controller and at the same time the entire amount shall be paid into the State Treasury and shall be credited to the Veterinary Medical Board Contingent Fund. This contingent fund shall be available, upon appropriation by the Legislature, for the use of the Veterinary Medical Board.

SEC. 37.

- SEC. 52. Section 4905 of the Business and Professions Code is amended to read:
- 4905. The following fees shall be collected by the board and shall be credited to the Veterinary Medical Board Contingent Fund:
- (a) The fee for filing an application for examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars (\$350).
- (b) The fee for the California state board examination shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed three hundred fifty dollars (\$350).
- (c) The fee for the Veterinary Medicine Practice Act examination shall be set by the board in an amount it determines reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed one hundred dollars (\$100).
- (d) The initial license fee shall be set by the board not to exceed five hundred dollars (\$500) except that, if the license is issued less than one year before the date on which it will expire, then the fee shall be set by the board not to exceed two hundred fifty dollars (\$250). The board may, by appropriate regulation, provide for the waiver or refund of the initial license fee where the license is issued
- 40 less than 45 days before the date on which it will expire.

SB 1193 — 74—

(e) The renewal fee shall be set by the board for each biennial renewal period in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed five hundred dollars (\$500).

- (f) The temporary license fee shall be set by the board in an amount it determines is reasonably necessary to provide sufficient funds to carry out the purpose of this chapter, not to exceed two hundred fifty dollars (\$250).
- (g) The fee for filing an application for a university license shall be one hundred twenty-five dollars (\$125), which may be revised by the board in regulation but shall not exceed three hundred fifty dollars (\$350).
- (h) The initial license fee for a university license shall be two hundred ninety dollars (\$290), which may be revised by the board in regulation but shall not exceed five hundred dollars (\$500).
- (i) The biennial renewal fee for a university license shall be two hundred ninety dollars (\$290), which may be revised by the board in regulation but shall not exceed five hundred dollars (\$500).
- (j) The delinquency fee shall be set by the board, not to exceed fifty dollars (\$50).
- (k) The fee for issuance of a duplicate license is twenty-five dollars (\$25).
- (1) Any charge made for duplication or other services shall be set at the cost of rendering the service, except as specified in subdivision (k).
- (m) The fee for failure to report a change in the mailing address is twenty-five dollars (\$25).
- (n) The initial and annual renewal fees for registration of veterinary premises shall be set by the board in an amount not to exceed four hundred dollars (\$400) annually.
- (o) If the money transferred from the Veterinary Medical Board Contingent Fund to the General Fund pursuant to the Budget Act of 1991 is redeposited into the Veterinary Medical Board Contingent Fund, the fees assessed by the board shall be reduced correspondingly. However, the reduction shall not be so great as to cause the Veterinary Medical Board Contingent Fund to have a reserve of less than three months of annual authorized board expenditures. The fees set by the board shall not result in a Veterinary Medical Board Contingent Fund reserve of more than 10 months of annual authorized board expenditures.

— 75 — **SB 1193**

SEC. 38. 1

2 SEC. 53. Section 13401.5 of the Corporations Code is amended 3 to read:

4 13401.5. Notwithstanding subdivision (d) of Section 13401 5 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees 6 7 of the professional corporations designated in this section so long 8 as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional 10 corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional 11 corporation so designated herein does not exceed the number of 12 13 persons licensed by the governmental agency regulating the 14 designated professional corporation. This section does not limit 15 employment by a professional corporation designated in this section to only those licensed professionals listed under each subdivision. 16 17 Any person duly licensed under Division 2 (commencing with 18 Section 500) of the Business and Professions Code, the 19 Chiropractic Act, or the Osteopathic Act may be employed to 20 render professional services by a professional corporation 21 designated in this section.

- 22 (a) Medical corporation.
- 23 (1) Licensed doctors of podiatric medicine.
- (2) Licensed psychologists. 24
- 25 (3) Registered nurses.
- 26 (4) Licensed optometrists.
- 27 (5) Licensed marriage and family therapists.
- 28 (6) Licensed clinical social workers.
- 29 (7) Licensed physician assistants.
- 30 (8) Licensed chiropractors.
- 31 (9) Licensed acupuncturists.
- 32 (10) Naturopathic doctors.
- 33 (11) Licensed professional clinical counselors.
- 34 (12) Licensed physical therapists.
- 35 (13) Licensed pharmacists.
- (b) Podiatric medical corporation. 36
- 37 (1) Licensed physicians and surgeons.
- 38 (2) Licensed psychologists.
- 39 (3) Registered nurses.
- 40 (4) Licensed optometrists.

SB 1193 — 76—

- 1 (5) Licensed chiropractors.
- 2 (6) Licensed acupuncturists.
- 3 (7) Naturopathic doctors.
- 4 (8) Licensed physical therapists.
- 5 (c) Psychological corporation.
- 6 (1) Licensed physicians and surgeons.
- 7 (2) Licensed doctors of podiatric medicine.
- 8 (3) Registered nurses.
- 9 (4) Licensed optometrists.
- 10 (5) Licensed marriage and family therapists.
- 11 (6) Licensed clinical social workers.
- 12 (7) Licensed chiropractors.
- 13 (8) Licensed acupuncturists.
- 14 (9) Naturopathic doctors.
- 15 (10) Licensed professional clinical counselors.
- 16 (d) Speech-language pathology corporation.
- 17 (1) Licensed audiologists.
- 18 (e) Audiology corporation.
- 19 (1) Licensed speech-language pathologists.
- 20 (f) Nursing corporation.
- 21 (1) Licensed physicians and surgeons.
- 22 (2) Licensed doctors of podiatric medicine.
- 23 (3) Licensed psychologists.
- 24 (4) Licensed optometrists.
- 25 (5) Licensed marriage and family therapists.
- 26 (6) Licensed clinical social workers.
- 27 (7) Licensed physician assistants.
- 28 (8) Licensed chiropractors.
- 29 (9) Licensed acupuncturists.
- 30 (10) Naturopathic doctors.
- 31 (11) Licensed professional clinical counselors.
- 32 (g) Marriage and family therapist corporation.
- 33 (1) Licensed physicians and surgeons.
- 34 (2) Licensed psychologists.
- 35 (3) Licensed clinical social workers.
- 36 (4) Registered nurses.
- 37 (5) Licensed chiropractors.
- 38 (6) Licensed acupuncturists.
- 39 (7) Naturopathic doctors.
- 40 (8) Licensed professional clinical counselors.

77 SB 1193

- 1 (h) Licensed clinical social worker corporation.
- 2 (1) Licensed physicians and surgeons.
- 3 (2) Licensed psychologists.
- 4 (3) Licensed marriage and family therapists.
- 5 (4) Registered nurses.
- 6 (5) Licensed chiropractors.
- 7 (6) Licensed acupuncturists.
- 8 (7) Naturopathic doctors.
- 9 (8) Licensed professional clinical counselors.
- 10 (i) Physician assistants corporation.
- 11 (1) Licensed physicians and surgeons.
- 12 (2) Registered nurses.
- 13 (3) Licensed acupuncturists.
- 14 (4) Naturopathic doctors.
- 15 (j) Optometric corporation.
- 16 (1) Licensed physicians and surgeons.
- 17 (2) Licensed doctors of podiatric medicine.
- 18 (3) Licensed psychologists.
- 19 (4) Registered nurses.
- 20 (5) Licensed chiropractors.
- 21 (6) Licensed acupuncturists.
- 22 (7) Naturopathic doctors.
- 23 (k) Chiropractic corporation.
- 24 (1) Licensed physicians and surgeons.
- 25 (2) Licensed doctors of podiatric medicine.
- 26 (3) Licensed psychologists.
- 27 (4) Registered nurses.
- 28 (5) Licensed optometrists.
- 29 (6) Licensed marriage and family therapists.
- 30 (7) Licensed clinical social workers.
- 31 (8) Licensed acupuncturists.
- 32 (9) Naturopathic doctors.
- 33 (10) Licensed professional clinical counselors.
- 34 (*l*) Acupuncture corporation.
- 35 (1) Licensed physicians and surgeons.
- 36 (2) Licensed doctors of podiatric medicine.
- 37 (3) Licensed psychologists.
- 38 (4) Registered nurses.
- 39 (5) Licensed optometrists.
- 40 (6) Licensed marriage and family therapists.

SB 1193 — 78—

- 1 (7) Licensed clinical social workers.
- 2 (8) Licensed physician assistants.
- 3 (9) Licensed chiropractors.
- 4 (10) Naturopathic doctors.
- 5 (11) Licensed professional clinical counselors.
- 6 (m) Naturopathic doctor corporation.
- 7 (1) Licensed physicians and surgeons.
- 8 (2) Licensed psychologists.
- 9 (3) Registered nurses.
- 10 (4) Licensed physician assistants.
- 11 (5) Licensed chiropractors.
- 12 (6) Licensed acupuncturists.
- 13 (7) Licensed physical therapists.
- 14 (8) Licensed doctors of podiatric medicine.
- 15 (9) Licensed marriage and family therapists.
- 16 (10) Licensed clinical social workers.
- 17 (11) Licensed optometrists.
- 18 (12) Licensed professional clinical counselors.
- 19 (n) Dental corporation.
- 20 (1) Licensed physicians and surgeons.
- 21 (2) Dental assistants.
- 22 (3) Registered dental assistants.
- 23 (4) Registered dental assistants in extended functions.
- 24 (5) Registered dental hygienists.
- 25 (6) Registered dental hygienists in extended functions.
- 26 (7) Registered dental hygienists in alternative practice.
- (o) Professional clinical counselor corporation.
- 28 (1) Licensed physicians and surgeons.
- 29 (2) Licensed psychologists.
- 30 (3) Licensed clinical social workers.
- 31 (4) Licensed marriage and family therapists.
- 32 (5) Registered nurses.
- 33 (6) Licensed chiropractors.
- 34 (7) Licensed acupuncturists.
- 35 (8) Naturopathic doctors.
- 36 (p) Physical therapy corporation.
- 37 (1) Licensed physicians and surgeons.
- 38 (2) Licensed doctors of podiatric medicine.
- 39 (3) Licensed acupuncturists.
- 40 (4) Naturopathic doctors.

-79 - SB 1193

- 1 (5) Licensed occupational therapists.
- 2 (6) Licensed speech-language therapists.
- 3 (7) Licensed audiologists.
- 4 (8) Registered nurses.
- 5 (9) Licensed psychologists.
 - (10) Licensed physician assistants.
- 7 (q) Registered dental hygienist in alternative practice 8 corporation.
- (1) Registered dental assistants.
- 10 (2) Licensed dentists.
- 11 (3) Registered dental hygienists.
- 12 (4) Registered dental hygienists in extended functions.
- 13 SEC. 39.

6

14 15

16

17

18

19

20

21

22

23

2425

26

27

28

29

30

31

32

33 34

35

36

37

38

39

40

- SEC. 54. Section 1261.6 of the Health and Safety Code is amended to read:
- 1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
- (2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.
- (3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.
- (b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.
- (c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.
- (d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and

SB 1193 — 80 —

maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

- (2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.
- (e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:
- (1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.
- (2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.
- (3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.
- (f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:
- (1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.
- (2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.
- (3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

—81 — SB 1193

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

- (5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
- (6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.
- (7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.
- (B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).
- (g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the

SB 1193 -82-

facility and be delivered to the facility if all of the following conditions are met:

- (1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
- (2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
- (3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.
- (h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
- (i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

SEC. 40.

- SEC. 55. Section 11164.5 of the Health and Safety Code is amended to read:
- 11164.5. (a) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be

83 SB 1193

changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(b) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

SEC. 56. Section 42.5 of this bill incorporates amendments to Section 4400 of the Business and Professions Code proposed by both this bill and Senate Bill 1039. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2017, (2) each bill amends Section 4400 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1039, in which case Section 42 of this bill shall not become operative.

SEC. 57. Section 47.5 of this bill incorporates amendments to Section 4830 of the Business and Professions Code proposed by both this bill and Senate Bill 1039. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2017, (2) each bill amends Section 4830 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1039, in which case Section 47 of this bill shall not become operative.

SEC. 41.

1 2

SEC. 58. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

SB 1193 — 84 —

- 1 the meaning of Section 6 of Article XIIIB of the California
- 2 Constitution.